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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/731,316

12/06/2000

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015225-005210US

1043

21968 7590 04/28/2009

NEKTAR THERAPEUTICS  
201 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

04/28/2009

PAPER

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 09/731,316  
Filing Date: December 06, 2000  
Appellant(s): SCHULER ET AL.

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SCHULER et al.  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 28 September 2007 appealing from the Office action mailed 6 October 2005.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,740,794	SMITH et al.	1-1998
WO 9944663	MCGINN et al.	9-1999
6,167,880	GONDA et al.	1-2007
5,694,920	ABRAMS et al.	12-1997

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1, 3-7, 11, 15, 16, 18, 21, 25-29, 38, 39, 45-49, 61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. 5740794 in view of McGinn et al. WO 99/44663.
2. Smith et al. teaches a method for conditioning a packaged powder, the method comprising: providing a receptacle 12 having an enclosed chamber containing an amount of a powder; and flowing a gas through the chamber to aerosolize the powder (col. 13, lines 22-35). Smith et al. fails to teach providing at least one pulse of energy to the receptacle.

McGinn et al. teaches a method using a common pulse of energy to release medicament (pg. 24, lines 8-18). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of McGinn et al. to release/deaggregate medicament for delivery to the patient.

3. Smith/McGinn teaches a method and system for conditioning a packaged powder, the method further comprising: releasing a spring loaded lever (pg. 27, lines

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12-19); bending the device and then quickly releasing the receptacle (pg. 22, line 24-25 and pg. 23, lines 1-7); moving the receptacle past an area that temporarily engages a portion of the receptacle (pg. 22, line 24-25 and pg. 23, lines 1-7); wherein the powder is composed of fine particles having a mean size in the range from 0.5 micrometer to about 5 micrometers (pg. 5, lines 14-15); wherein the receptacle further comprises a metallic body having a tube extending from the chamber (pg. 16, lines 12-15); a container having an enclosure, and wherein the mechanism is coupled to the container, wherein the container comprises a base and a cover that is pivotally coupled to the base (figs. 1 and 2); a coupling arrangement that couples the receptacle to the base (fig. 2); an aerosolization system comprising a mouthpiece 72.

4. As to claim 4, Smith/McGinn teaches the method as in claim 3. It should be noted fails to specifically teach striking the receptacle with an amount of energy of at least about 0.01 lbf-in. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to strike the receptacle at a force strong enough to provide sufficient energy to deaggregate the powder. The limitations as claimed can be obtained through routine observation and experimentation.

Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

5. As to claim 46-48, Smith/McGinn teaches a kit for aerosolizing a powder, comprising: at least one receptacle having an enclosed chamber; and an aerosolization device having an opening. It should be noted that McGinn et al. does not specifically

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teach instructions. However, it would have been inherent to include instructions for proper use of the kit to insure optimum results.

6. As to claim 49, Smith/McGinn teaches a kit as in claim 48, wherein the powder conditioning device comprises a frame and a spring-loaded lever are pivotally coupled to the frame, wherein the lever are is releasable to strike the receptacle.

7. As to claim 62, Smith/McGinn fails to teach wherein the pulse of energy is provided within about 100 ms before actuation of the aerosolization system to about 23 ms after the actuation of the aerosolization system. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made provide the pulse of energy during the range set forth in the claim to insure complete inhalation of the medication. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

8. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Smith/McGinn in further view of Gonda et al. 6167880.

9. As to claim 2, Smith/McGinn teaches the method as in claim 1. It should be noted that Smith/McGinn fails to teach providing the pulse of energy while the powder is sealed within the chamber.

Gonda teaches a common method of providing a pulse of energy in a sealed chamber to deaggregate/aerosolize the powder before inhalation. Therefore it would have been obvious to one of ordinary skill in the art to modify the method of

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Smith/McGinn to include the method step of Gonda et al. to deaggregate/aerosolize the powder before inhalation (col. 41, lines 59-62).

10. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Smith/McGinn in further view of Abrams et al 5694920.

11. As to claim 12, Smith/McGinn teaches the method as in claim 1. It should be noted that Smith/McGinn fails to teach providing at least one pre-conditioning step prior to providing the at least one pulse of energy, wherein the pre-conditioning step comprises vibrating the receptacle for a predetermined period of time.

Abrams et al. teaches a common method of pre-conditioning to provide only deaggregated drug particle are used. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Smith/McGinn to include the method step of Abrams et al. to obtain only smaller sized deaggregated particles (col. 6, lines 18-19).

12. Claims 1, 8-11, 13-15, 23, 24, 26, 27, 37, 43-45, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. in view of Abrams et al. 5694920.

13. Smith et al. teaches a method for conditioning a packaged powder, the method comprising: providing a receptacle 12 having an enclosed chamber containing an amount of a powder; and flowing a gas through the chamber to aerosolize the powder (col. 13, lines 22-35). Smith et al. fails to teach providing at least one pulse of energy to the receptacle.

Abrams et al. teaches a method using a common pulse of energy to deaggregate medicament (col. 7, lines 42-44). Therefore it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to include the step of Abrams et al. to release/deaggregate medicament for delivery to the patient.

14. Smith/Abrams teaches a method and system for conditioning a packaged powder, the method and system further comprising: providing at least one pulse of energy comprising providing a pulse of vibratory energy (col. 7, lines 42-44); contacting the receptacle with a vibrating piezoelectric transducer (col. 7, lines 42-44); wherein the powder is composed of fine particle having a mean size in the range from about 0.5 micrometers to about 5 micrometers (col. 1, lines 40-43); an aerosolization system comprising a mouthpiece 218.

15. As to claims 10 and 13, Smith/Abrams teaches the method as in claim 9. It should be noted that Smith/Abrams fails to teach vibrating the transducer at a frequency of at least about 10 kHz. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vibrate the transducer at a frequency high enough to provide sufficient energy to deaggregate and/or aerosolize the powder to sufficient size to be inhaled by the user. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

16. As to claim 14, Smith/Abrams teaches the method as in claim 1. It should be noted that Smith/Abrams fails to teach wherein the receptacle is vibrated for about 0.01 minute to about 10 minutes. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vibrate the receptacle for



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an amount of time long enough to deaggregate the powder. The limitations as claimed can be obtained through routine observation and experimentation. Furthermore, the Applicant has not disclosed why the particulars of limitations are of importance or solve a stated problem or provide an advantage over the prior art.

#### **(10) Response to Argument**

The appellant argues that there is no reason for the combination of Smith et al. and McGinn et al. The examiner disagrees. Smith et al. teaches that it is advantageous to deagglomerate/fluidize agglomerates in a receptacle prior to aerosolization. The method of fluidization is provided by a jet/pulse of air provided directly to the agglomerate in a receptacle/chamber then extracting the fluidized powder by an airstream. McGinn et al. teaches an alternative method to fluidizing an agglomerate by providing a mechanical pulse to a cartridge prior to inhalation (aerosolization). As stated by Smith et al. it is desirable that powder agglomerates present in dry powder be sufficiently broken up prior to inhalation (col. 1, line 64 – col. 2, line 2). The mechanical pulse provided of McGinn et al. provided to the receptacle of Smith et al. is an obvious alternative to the pulse of air provided to the powder itself to deagglomerate/fluidize for breaking up the agglomerate. The same applies for Abrams et al. Abrams et al. teaches an alternative to using a pulse of air to deagglomerate/fluidize to break up powder agglomerates. Both McGinn et al. and Abram et al. increase inhalation efficiency by braking up agglomerates.

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**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Michael Mendoza

/Michael G. Mendoza/

Examiner, Art Unit 3734

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